Amendments to the Claims

This listing of claims will replace all prior versions, and listings of claims in the application.

1. (original) A method of producing a formulation comprising:

(a) mixing

(i) a cationic surfactant;

(ii) a polyoxyethylene (POE) and polyoxypropylene (POP) block copolymer; and

(iii) a polynucleotide;

at a temperature below the cloud point of said block copolymer to form a mixture; and

(b) cold filtering the mixture to produce a sterile formulation.

2. (original) The method of claim 1, further comprising:

(c) raising the temperature of the mixture above the cloud point of said block copolymer prior to step (b).

3. (original) The method of claim 1, further comprising:

(c) raising the temperature of the mixture above the cloud point of said block copolymer after step (b).

4. (original) The method of claim 1, further comprising:

(c) raising the temperature of the mixture above the cloud point of said block copolymer prior to step (b);

(d) lowering the temperature to below the cloud point of said block copolymer; and

(e) repeating steps (c) and (d) about 1 to about 50 times prior to step (b).

5. (original) The method of claim 1, further comprising:

(c) raising the temperature of the mixture above the cloud point of said block copolymer after step (b);

(d) lowering the temperature to below the cloud point of said block copolymer; and

(e) repeating steps (c) and (d) about 1 to about 50 times.

6. (currently amended) The method of claim 1 ~~any one of claims 1-5~~, further comprising aliquoting said formulation into a suitable container.

7. (currently amended) The method of claim 1 ~~any one of claims 1-5~~, wherein said block copolymer is of the general formula:

$HO(C_2H_4O)_x(C_3H_6O)_y(C_2H_4O)_xH$; wherein (y) represents a number such that the molecular weight of the hydrophobic POP portion (C_3H_6O) is up to approximately 20,000 daltons and wherein (x) represents a number such that the percentage of the hydrophilic POE portion (C_2H_4O) is between approximately 1% and 50% by weight.

8. (currently amended) The method of ~~any one of~~ claim 7, wherein said block copolymer is the poloxamer CRL-1005.

9. (currently amended) The method of claim 1 ~~any one of claims 1-5~~, wherein said block copolymer is of the general formula: $HO(C_3H_6O)_y(C_2H_4O)_x(C_3H_6O)_yH$ wherein (y) represents a number such that the molecular weight of the hydrophobic POP portion (C_3H_6O) is up to approximately 20,000 daltons and wherein (x) represents a number such that the percentage of hydrophilic POE portion (C_2H_4O) is between approximately 1% and 50% by weight.

10. (currently amended) The method of claim 1 ~~any one of claims 1-5~~, wherein the cationic surfactant is selected from the group consisting of benzalkonium chloride, benethonium chloride, cetrimide, cetylpyridinium chloride, acetyl triethylammonium chloride, Bn-DHxRIE, DHxRIE-OAc, DHxRIE-OBz and Pr-DOctRIE-OAc.

11. (original) The method of claim 1, wherein step (a) is performed at a temperature of about -2°C to about 8°C.

12. (original) The method of claim 2, wherein said step (c) is performed at a temperature of about 8°C to about 35°C.

13. (original) The method of claim 3, wherein said step (c) is performed at a temperature of about 8°C to about 35°C.

14. (original) The method of claim 4, wherein said step (c) is performed at a temperature of about 8°C to about 35°C.

15. (original) The method of claim 5, wherein said step (c) is performed at a temperature of about 8°C to about 35°C.

16. (original) The method of claim 4, wherein said step (d) is performed at a temperature of about -2°C to about 8°C.

17. (original) The method of claim 5, wherein said step (d) is performed at a temperature of about -2°C to about 8°C.

18. (currently amended) The method of claim 1 ~~any one of claims 1-5~~, wherein said cold filtering is performed at a temperature of about -2°C to about 8°C.

19. (currently amended) The method of claim 1 ~~any one of claims 1-5~~, wherein said cold filtering is performed using a filter with a pore size of about 0.01 microns to about 2 microns.

20. (currently amended) The method of claim 1 ~~any one of claims 1-5~~, wherein the final concentration of said cationic surfactant present in said formulation is from about 0.01mM to about 5mM.

21. (currently amended) The method of claim 1 ~~any one of claims 1-5~~, wherein the final concentration of said block copolymer present in said formulation is from about 1 mg/mL to about 50 mg/mL.

22. (currently amended) The method of claim 1 ~~any one of claims 1-5~~, wherein the final concentration of said polynucleotide ~~molecules~~ present in said formulation is from about 1 ng/mL to about 10 mg/mL.

23. (original) A cationic lipid selected from the group consisting of: Bn-DHxRIE, DHxRIE-OAc, DHxRIE-OBz and Pr-DOctRIE-OAc.

24. (original) The cationic lipid of claim 23, wherein said lipid is Bn-DHxRIE.

25. (original) The cationic lipid of claim 23, wherein said lipid is DHxRIE-OAc.

26. (original) The cationic lipid of claim 23, wherein said lipid is DHxRIE-OBz.

27. (original) The cationic lipid of claim 23, wherein said lipid is Pr-DOctRIE-OAc.